

FEB 16 2001

Approval Date: _____

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FREEDOM OF INFORMATION SUMMARY

ORIGINAL NEW ANIMAL DRUG APPLICATION

NADA 141-142

**Amprolium (AMPROL®) plus
Bacitracin methylene disalicylate (BMD®) plus
Roxarsone (3-NITRO®)**

For development of active immunity to coccidiosis, as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in replacement chickens.

Sponsored by:

**Alpharma Inc.
One Executive Drive
Fort Lee, NJ 07024**

F0151

FREEDOM OF INFORMATION SUMMARY

Combined use of AMPROL[®], BMD[®], and 3-NITRO[®] in Replacement Chicken Feeds

I. GENERAL INFORMATION:

NADA: 141-142

Sponsor: Alpharma Inc.
One Executive Drive
Fort Lee, NJ 07024

Generic Names: Amprolium
Bacitracin methylene disalicylate
Roxarsone

Trade Names: AMPROL[®]
BMD[®]
3-NITRO[®]

Marketing Status: OTC

II. INDICATIONS FOR USE:

For development of active immunity to coccidiosis, as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in replacement chickens.

III. DOSAGE:

- A. Dosage form: This NADA provides for the combined use of these three Type A medicated articles, amprolium as per 21 CFR 558.55(d)(2)(i), bacitracin methylene disalicylate as per 21 CFR 558.76(d)(1)(vi), and roxarsone as per 21 CFR 558.530(d)(1). Amprolium is supplied as a Type A medicated article in a single concentration of 25 percent amprolium. Bacitracin methylene disalicylate is supplied as a Type A medicated article in concentrations of 10, 25, 30, 40, 50, 60, or 75 grams bacitracin activity per pound. Roxarsone is supplied as a Type A medicated article in concentrations of 45.4, 90, 227 or 360 grams of roxarsone activity per pound.
- B. Route of Administration: Oral, *via* the feed.

C. Recommended Dosage:

Amprolium

Amprolium is added to replacement chicken feed at concentrations of 36.3 to 113.5 grams/ton for the development of active immunity to coccidiosis.

Bacitracin methylene disalicylate

Bacitracin methylene disalicylate is added to replacement chicken feed at a concentration of 50 grams/ton as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.

Roxarsone

Roxarsone is added to growing chicken feed at a concentration of 22.7 to 45.4 grams/ton for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

IV. EFFECTIVENESS:

In accordance with the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Animal Drug Availability Act of 1996, if the animal drugs/active ingredients intended for use in combination in animal feed have previously been separately approved for the particular uses and conditions of use for which they are intended for use in combination, FDA will not refuse to approve an NADA for the combination on effectiveness grounds unless the Agency finds that the NADA fails to demonstrate that 1) there is substantial evidence to indicate that any active ingredient or animal drug intended only for the same use as another active ingredient or animal drug in the combination makes a contribution to the labeled effectiveness, 2) each of the active ingredients or animal drugs intended for at least one use that is different from all other active ingredients or animal drugs used in the combination provides appropriate concurrent use for the intended target population, or 3) where the combination contains more than one nontopical antibacterial active ingredient/animal drug, there is substantial evidence that each of the nontopical antibacterial active ingredients or animal drugs makes a contribution to the labeled effectiveness.

Amprolium, as provided by Merial, has previously been separately approved for use in replacement chickens for the development of active immunity to coccidiosis (21 CFR 558.55(d)(2)(i)). Bacitracin methylene disalicylate as provided by Alpharma Inc., has previously been separately approved for replacement chickens as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin (21 CFR 558.76(d)(1)(vi)). Roxarsone, as provided by Alpharma Inc., has

previously been separately approved for increased rate of weight gain, improved feed efficiency, and improved pigmentation in growing chickens (21 CFR 558.530(d)(1)). Effectiveness for each drug, amprolium, bacitracin methylene disalicylate, and roxarsone when administered alone in accordance with its approved uses and conditions of use, is demonstrated in Merial's approved NADA 012-350, to which Alpharma Inc. has a right of reference, and in Alpharma Inc.'s approved NADA 46-592 and 7-891, respectively.

Because amprolium, bacitracin methylene disalicylate, and roxarsone each have at least one use that is different from all other animal drugs used in the combination, the NADA must also demonstrate that amprolium plus bacitracin methylene disalicylate plus roxarsone provide appropriate concurrent use for the intended target population. The use of amprolium plus bacitracin methylene disalicylate plus roxarsone provide appropriate concurrent use because these drugs are intended to treat different conditions (amprolium, coccidiosis; bacitracin methylene disalicylate, necrotic enteritis; roxarsone, pigmentation problems) likely to occur simultaneously with sufficient frequency in replacement chickens. There is no more than one nontopical antibacterial (bacitracin methylene disalicylate) contained in this combination animal drug intended for use in Type C medicated feed. Amprolium is not considered to be an antibacterial animal drug for such use in chickens for the purposes of section 512(d)(4) of the FFDCA, because amprolium is approved only for prevention of a protozoal disease (coccidiosis) in replacement chickens. Roxarsone is not considered to be an antibacterial animal drug for such use in replacement chickens for the purposes of section 512(d)(4) of the FFDCA, because roxarsone is not approved for use in chickens for the diagnosis, cure, mitigation, treatment or prevention of bacterial disease and is not approved for any other use the Center for Veterinary Medicine deems attributable to its antibacterial properties.

V. ANIMAL SAFETY:

In accordance with the FFDCA, as amended by the Animal Drug Availability Act of 1996, if the active ingredients or animal drugs intended for use in combination have previously been separately approved for the particular uses and conditions of use for which they are intended for use in combination, FDA will not refuse to approve an NADA for the combination on target animal safety grounds unless there is a substantiated scientific issue specific to an active ingredient or animal drug used in the combination, or a scientific issue is raised by target animal observations contained in studies submitted to the NADA for the combination and FDA finds that the application fails to establish that such a combination active ingredient or animal drug is safe for the target animal.

Amprolium, as provided by Merial, has previously been separately approved for use in replacement chickens for the development of active immunity to coccidiosis (21 CFR 558.55(d)(2)(i)). Bacitracin methylene disalicylate as provided by Alpharma Inc., has previously been separately approved for replacement chickens as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to

bacitracin methylene disalicylate (21 CFR 558.76(d)(1)(vi)). Roxarsone, as provided by Alpha Pharma Inc., has previously been separately approved for increased rate of weight gain, improved feed efficiency, and improved pigmentation in growing chickens (21 CFR 558.530(d)(1)). Target animal safety for each drug, when administered alone in accordance with its approved uses and conditions of use, is demonstrated in Merial's approved NADA 012-350, to which Alpha Pharma Inc. has a right of reference, and in Alpha Pharma Inc.'s approved NADA 46-592 and 7-891, respectively. The Agency has found no substantiated scientific issue relating to the target animal safety of amprolium, bacitracin methylene disalicylate, or roxarsone when used in combination under this NADA and no scientific issue has been raised by target animal observations submitted as part of the NADA for this combination. Thus, pursuant to FFDCA, as amended by the Animal Drug Availability Act of 1996, no specific target animal safety studies are required for approval of NADA 141-142.

VI. HUMAN SAFETY:

A. Tolerances

Data establishing the safety of amprolium, bacitracin methylene disalicylate, and roxarsone have been established by NADA 12-350, 46-592, and 7-891, respectively. Tolerances for residues of amprolium (1-(4-amino-2-n-propyl-5-pyrimidinylmethyl)-2-picolinium chloride hydrochloride) are established at 1 ppm in uncooked liver and kidney, 0.5 ppm in uncooked muscle, 8 ppm in egg yolks, and 4 ppm in whole eggs (21 CFR 556.50). Tolerances for residues of bacitracin in uncooked edible tissues of chickens are established at 0.5 ppm (0.02 unit/g) in 21 CFR 556.70. Tolerances for residues of arsenic from roxarsone in chickens are established at 0.5 ppm in uncooked muscle tissue, 2 ppm in uncooked edible by-products and 0.5 ppm in eggs (21 CFR 556.60).

B. Residue Data

In support of the safety of edible tissues, a residue study was performed in chickens. Day-old chicks were fed either non-medicated ration or a ration containing 25 g bacitracin methylene disalicylate per ton and 0.005% roxarsone in combination with 0.0125% amprolium and 0.004% ethopabate for 5 weeks. At that time the treated birds were divided into separate groups and given rations containing 50 g bacitracin methylene disalicylate per ton with the other 3 drugs, roxarsone alone, or 50 g bacitracin methylene disalicylate with Amprol-HiE for 4 weeks. At the conclusion of the experiment, birds were slaughtered and drug residues determined. Residues for each drug were below their respective tolerances by the five day withdrawal period required by roxarsone. In addition these data support the current combination approval of amprolium, ethopabate, bacitracin methylene disalicylate and roxarsone under NADA 49-180.

Non-interference among the active ingredients (amprolium, bacitracin methylene disalicylate, and roxarsone) in tissue residue depletion at the longest withdrawal time (5 days) and in the performance of the analytical methods for tissue residues was demonstrated.

The available residue chemistry information supports the assignment of a five day withdrawal period for replacement chickens fed the combination of amprolium (36.3-113.5 g/ton), bacitracin methylene disalicylate (50 g/ton), and roxarsone (22.7-45.4 g/ton).

C. Regulatory Methods for Residues

A spectrophotometric method is used to assay tissues for roxarsone residues. The method entitled "Arsenic (Total) Residues in Animal Tissues, Spectrophotometric Method" is published in the AOAC, 16th Edition. The method is on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

The regulatory analytical method for detection of residues of amprolium is a fluorimetric test. The method is on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

A microbiological method is used to assay tissues for bacitracin residues. The method entitled "Modified Microbiological Method for Determination of Bacitracin in Tissues". The method is on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

VII. AGENCY CONCLUSIONS:

The data submitted in support of this NADA comply with the requirements of Section 512 of the FFDCA and demonstrate that amprolium (36.3 to 113.5 g/ton) plus bacitracin methylene disalicylate (50 g/ton) plus roxarsone (22.7 to 45.4 g/ton) are safe and effective for the claims indicated in section II of this FOI Summary.

Pursuant to 21 CFR 514.106(b)(2)(vi), this combination NADA approval is regarded as a Category II supplemental change which does not require a reevaluation of safety and efficacy data in the parent NADAs. The drugs are to be fed in Type C medicated feeds, in accordance with section II and III of the FOI Summary and the Blue Bird labeling that is attached to this document.

Because higher levels of the drugs used in this combination are currently being used in combination, this combination does not pose an increased risk to human food safety and the five day withdrawal period is adequate.

Attached labeling: Type C Medicated Feed (Blue Bird) - Replacement chickens

Net weight lb (kg) on bag or bulk

Amprolium-SV1/Bacitracin methylene disalicylate/Roxarsone
Replacement Chicken Ration
Type C Medicated Feed

For the development of active immunity to coccidiosis, as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in replacement chickens.

Active Drug Ingredient

Amprolium.....	113.5 g/ton
Bacitracin methylene disalicylate	50 g/ton
Roxarsone.....	22.7 to 45.4 g/ton

Guaranteed Analysis

Crude Protein, not less than.....	_____ %
Lysine, not less than.....	_____ %
Methionine, not less than.....	_____ %
Crude Fat, not less than.....	_____ %
Crude Fiber, not more than.....	_____ %
Calcium, not less than.....	_____ %
Calcium, not more than.....	_____ %
Phosphorus, not less than.....	_____ %
Salt ¹ , not less than.....	_____ %
Salt ¹ , not more than.....	_____ %
Sodium ² , not less than.....	_____ %
Sodium ² , not more than.....	_____ %

¹If added.

²Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

Ingredients

Each ingredient must be specifically named in accordance with the names and definitions adopted by the Association of American Feed Control Officials.

Directions for Use

Feed continuously as sole ration under conditions of severe exposure to coccidiosis up to 5 weeks of age.

(OVER)

WARNING: Do not feed to laying chickens. Withdraw 5 days before slaughter.

CAUTION: Feed as sole source of organic arsenic. Feed as sole source of amprolium. Drug overdose or lack of water may result in leg weakness or paralysis. Do not use in feed containing bentonite.

MANUFACTURED BY

BLUE BIRD FEED MILL

Anytown, USA 12345

Net weight lb (kg) on bag or bulk
Amprolium-SV2/Bacitracin methylene disalicylate/Roxarsone
Replacement Chicken Ration
Type C Medicated Feed

For the development of active immunity to coccidiosis, as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in replacement chickens.

Active Drug Ingredient

Amprolium.....	72.6 to 113.5 g/ton
Bacitracin methylene disalicylate	50 g/ton
Roxarsone.....	22.7 to 45.4 g/ton

Guaranteed Analysis

Crude Protein, not less than.....	_____ %
Lysine, not less than.....	_____ %
Methionine, not less than.....	_____ %
Crude Fat, not less than.....	_____ %
Crude Fiber, not more than.....	_____ %
Calcium, not less than.....	_____ %
Calcium, not more than.....	_____ %
Phosphorus, not less than.....	_____ %
Salt ¹ , not less than.....	_____ %
Salt ¹ , not more than.....	_____ %
Sodium ² , not less than.....	_____ %
Sodium ² , not more than.....	_____ %

¹If added.

²Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

Ingredients

Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials.

Directions for Use

Feed continuously as sole ration under conditions of severe exposure to coccidiosis from 5 to 8 weeks of age.

WARNING: Do not feed to laying chickens. Withdraw 5 days before slaughter.

(OVER)

CAUTION: Feed as sole source of organic arsenic. Feed as sole source of amprolium. Drug overdose or lack of water may result in leg weakness or paralysis. Do not use in feed containing bentonite.

MANUFACTURED BY

BLUE BIRD FEED MILL
Anytown, USA 12345

Net weight lb (kg) on bag or bulk
Amprolium-SV3/Bacitracin methylene disalicylate/Roxarsone
Replacement Chicken Ration
Type C Medicated Feed

For the development of active immunity to coccidiosis, as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in replacement chickens.

Active Drug Ingredient

Amprolium.....	36.3 to 113.5 g/ton
Bacitracin methylene disalicylate	50 g/ton
Roxarsone.....	22.7 to 45.4 g/ton

Guaranteed Analysis

Crude Protein, not less than.....	_____ %
Lysine, not less than.....	_____ %
Methionine, not less than.....	_____ %
Crude Fat, not less than.....	_____ %
Crude Fiber, not more than.....	_____ %
Calcium, not less than.....	_____ %
Calcium, not more than.....	_____ %
Phosphorus, not less than.....	_____ %
Salt ¹ , not less than.....	_____ %
Salt ¹ , not more than.....	_____ %
Sodium ² , not less than.....	_____ %
Sodium ² , not more than.....	_____ %

¹If added.

²Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

Ingredients

Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials.

Directions for Use

Feed continuously as sole ration under conditions of severe exposure to coccidiosis over 8 weeks of age.

(OVER)

WARNING: Do not feed to laying chickens. Withdraw 5 days before slaughter.

CAUTION: Feed as sole source of organic arsenic. Feed as sole source of amprolium. Drug overdose or lack of water may result in leg weakness or paralysis. Do not use in feed containing bentonite.

MANUFACTURED BY

BLUE BIRD FEED MILL

Anytown, USA 12345

Net weight lb (kg) on bag or bulk
Amprolium-M1/Bacitracin methylene disalicylate/Roxarsone
Replacement Chicken Ration
Type C Medicated Feed

For the development of active immunity to coccidiosis, as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in replacement chickens.

Active Drug Ingredient

Amprolium.....	72.6 to 113.5 g/ton
Bacitracin methylene disalicylate	50 g/ton
Roxarsone.....	22.7 to 45.4 g/ton

Guaranteed Analysis

Crude Protein, not less than.....	_____ %
Lysine, not less than.....	_____ %
Methionine, not less than.....	_____ %
Crude Fat, not less than.....	_____ %
Crude Fiber, not more than.....	_____ %
Calcium, not less than.....	_____ %
Calcium, not more than.....	_____ %
Phosphorus, not less than.....	_____ %
Salt ¹ , not less than.....	_____ %
Salt ¹ , not more than.....	_____ %
Sodium ² , not less than.....	_____ %
Sodium ² , not more than.....	_____ %

¹If added.

²Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

Ingredients

Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials.

Directions for Use

Feed continuously as sole ration under conditions of moderate exposure to coccidiosis up to 5 weeks of age.

(OVER)

WARNING: Do not feed to laying chickens. Withdraw 5 days before slaughter.

CAUTION: Feed as sole source of organic arsenic. Feed as sole source of amprolium. Drug overdose or lack of water may result in leg weakness or paralysis. Do not use in feed containing bentonite.

MANUFACTURED BY

BLUE BIRD FEED MILL

Anytown, USA 12345

Net weight lb (kg) on bag or bulk

Amprolium-M2/Bacitracin methylene disalicylate/Roxarsone
Replacement Chicken Ration
Type C Medicated Feed

For the development of active immunity to coccidiosis, as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in replacement chickens.

Active Drug Ingredient

Amprolium.....	54.5 to 113.5 g/ton
Bacitracin methylene disalicylate	50 g/ton
Roxarsone.....	22.7 to 45.4 g/ton

Guaranteed Analysis

Crude Protein, not less than.....	_____ %
Lysine, not less than.....	_____ %
Methionine, not less than.....	_____ %
Crude Fat, not less than.....	_____ %
Crude Fiber, not more than.....	_____ %
Calcium, not less than.....	_____ %
Calcium, not more than.....	_____ %
Phosphorus, not less than.....	_____ %
Salt ¹ , not less than.....	_____ %
Salt ¹ , not more than.....	_____ %
Sodium ² , not less than.....	_____ %
Sodium ² , not more than.....	_____ %

¹If added.

²Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

Ingredients

Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials.

Directions for Use

Feed continuously as sole ration under conditions of moderate exposure to coccidiosis from 5 to 8 weeks of age.

(OVER)

WARNING: Do not feed to laying chickens. Withdraw 5 days before slaughter.

CAUTION: Feed as sole source of organic arsenic. Feed as sole source of amprolium. Drug overdose or lack of water may result in leg weakness or paralysis. Do not use in feed containing bentonite.

MANUFACTURED BY

BLUE BIRD FEED MILL
Anytown, USA 12345

Net weight lb (kg) on bag or bulk

Amprolium-M3/Bacitracin methylene disalicylate/Roxarsone
Replacement Chicken Ration
Type C Medicated Feed

For the development of active immunity to coccidiosis, as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in replacement chickens.

Active Drug Ingredient

Amprolium.....	36.3 to 113.5 g/ton
Bacitracin methylene disalicylate	50 g/ton
Roxarsone.....	22.7 to 45.4 g/ton

Guaranteed Analysis

Crude Protein, not less than.....	_____ %
Lysine, not less than.....	_____ %
Methionine, not less than.....	_____ %
Crude Fat, not less than.....	_____ %
Crude Fiber, not more than.....	_____ %
Calcium, not less than.....	_____ %
Calcium, not more than.....	_____ %
Phosphorus, not less than.....	_____ %
Salt ¹ , not less than.....	_____ %
Salt ¹ , not more than.....	_____ %
Sodium ² , not less than.....	_____ %
Sodium ² , not more than.....	_____ %

¹If added.

²Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

Ingredients

Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials.

Directions for Use

Feed continuously as sole ration under conditions of moderate exposure to coccidiosis over 8 weeks of age.

(OVER)

WARNING: Do not feed to laying chickens. Withdraw 5 days before slaughter.

CAUTION: Feed as sole source of organic arsenic. Feed as sole source of amprolium.
Drug overdose or lack of water may result in leg weakness or paralysis. Do not use in feed containing bentonite.

MANUFACTURED BY

BLUE BIRD FEED MILL

Anytown, USA 12345

Net weight lb (kg) on bag or bulk

Amprolium-S1/Bacitracin methylene disalicylate/Roxarsone
Replacement Chicken Ration
Type C Medicated Feed

For the development of active immunity to coccidiosis, as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in replacement chickens.

Active Drug Ingredient

Amprolium.....	36.3 to 113.5 g/ton
Bacitracin methylene disalicylate	50 g/ton
Roxarsone.....	22.7 to 45.4 g/ton

Guaranteed Analysis

Crude Protein, not less than.....	_____ %
Lysine, not less than.....	_____ %
Methionine, not less than.....	_____ %
Crude Fat, not less than.....	_____ %
Crude Fiber, not more than.....	_____ %
Calcium, not less than.....	_____ %
Calcium, not more than.....	_____ %
Phosphorus, not less than.....	_____ %
Salt ¹ , not less than.....	_____ %
Salt ¹ , not more than.....	_____ %
Sodium ² , not less than.....	_____ %
Sodium ² , not more than.....	_____ %

¹If added.

²Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

Ingredients

Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials.

Directions for Use

Feed continuously as sole ration under conditions of slight exposure to coccidiosis up to 5 weeks of age.

(OVER)

WARNING: Do not feed to laying chickens. Withdraw 5 days before slaughter.

CAUTION: Feed as sole source of organic arsenic. Feed as sole source of amprolium. Drug overdose or lack of water may result in leg weakness or paralysis. Do not use in feed containing bentonite.

MANUFACTURED BY

BLUE BIRD FEED MILL

Anytown, USA 12345

Net weight lb (kg) on bag or bulk
Amprolium-S2/Bacitracin methylene disalicylate/Roxarsone
Replacement Chicken Ration
Type C Medicated Feed

For the development of active immunity to coccidiosis, as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in replacement chickens.

Active Drug Ingredient

Amprolium.....	36.3 to 113.5 g/ton
Bacitracin methylene disalicylate	50 g/ton
Roxarsone.....	22.7 to 45.4 g/ton

Guaranteed Analysis

Crude Protein, not less than.....	_____ %
Lysine, not less than.....	_____ %
Methionine, not less than.....	_____ %
Crude Fat, not less than.....	_____ %
Crude Fiber, not more than.....	_____ %
Calcium, not less than.....	_____ %
Calcium, not more than.....	_____ %
Phosphorus, not less than.....	_____ %
Salt ¹ , not less than.....	_____ %
Salt ¹ , not more than.....	_____ %
Sodium ² , not less than.....	_____ %
Sodium ² , not more than.....	_____ %

¹If added.

²Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

Ingredients

Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials.

Directions for Use

Feed continuously as sole ration under conditions of slight exposure to coccidiosis from 5 to 8 weeks of age.

(OVER)

WARNING: Do not feed to laying chickens. Withdraw 5 days before slaughter.

CAUTION: Feed as sole source of organic arsenic. Feed as sole source of amprolium. Drug overdose or lack of water may result in leg weakness or paralysis. Do not use in feed containing bentonite.

MANUFACTURED BY

BLUE BIRD FEED MILL

Anytown, USA 1234

Net weight lb (kg) on bag or bulk

Amprolium-S3/Bacitracin methylene disalicylate/Roxarsone
Replacement Chicken Ration
Type C Medicated Feed

For the development of active immunity to coccidiosis, as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in replacement chickens.

Active Drug Ingredient

Amprolium.....	36.3 to 113.5 g/ton
Bacitracin methylene disalicylate	50 g/ton
Roxarsone.....	22.7 to 45.4 g/ton

Guaranteed Analysis

Crude Protein, not less than.....	_____ %
Lysine, not less than.....	_____ %
Methionine, not less than.....	_____ %
Crude Fat, not less than.....	_____ %
Crude Fiber, not more than.....	_____ %
Calcium, not less than.....	_____ %
Calcium, not more than.....	_____ %
Phosphorus, not less than.....	_____ %
Salt ¹ , not less than.....	_____ %
Salt ¹ , not more than.....	_____ %
Sodium ² , not less than.....	_____ %
Sodium ² , not more than.....	_____ %

¹If added.

²Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

Ingredients

Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials.

Directions for Use

Feed continuously as sole ration under conditions of slight exposure to coccidiosis over 8 weeks of age.

(OVER)

WARNING: Do not feed to laying chickens. Withdraw 5 days before slaughter.

CAUTION: Feed as sole source of organic arsenic. Feed as sole source of amprolium. Drug overdose or lack of water may result in leg weakness or paralysis. Do not use in feed containing bentonite.

MANUFACTURED BY

BLUE BIRD FEED MILL

Anytown, USA 12345